C11
C6 119

130. A method according to Claim 128 wherein the aneurysm is a cerebral aneurysm.

REMARKS

Applicant understands that claims 103-132 have been renumbered as claims 102-131. By way of this response, Applicant has formally amended the numbering of the claims to be consistent with the PTO's renumbering of the claims. Accordingly, prior to this response, claims 102-131 were pending.

By way of this response, 102, 103, 105-110, 112-120, 122-125, and 127-130 have been amended, and claims 104, 111, 121, 126, and 131 have been cancelled. Accordingly, claims 102, 103, 105-110, 112-120, 122-125, and 127-130 are now pending.

Applicant acknowledges that claims 112-114 have been rejected under 35 U.S.C. § 112. Applicant addresses those rejections herein.

Also, concurrently with filing of this amendment, Applicant is filing a supplemental Information Disclosure Statement (IDS) citing an additional publication reference which was discussed with the Examiner by telephone on September 24, 2002. Applicant thanks the Examiner for taking time to participate in the recent telephone discussions.

Item 1 of the Office Action - Specification

In the office action, the disclosure was objected to due to a typographical error and for allegedly failing to provid prop r antecedent support for the claimed subject matter

(i.e., the subject matter of claims 113 and 114). By the foregoing amendment Applicant has amended the specification to address these issues. This added description is clearly shown in the drawings and does not constitute new matter. Accordingly, all objections to the specification have been overcome.

Item 2 of the Office Action - Claim Rejections Under 35 U.S.C. § 112

Claims 110-118, and 128-130 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. In particular, the Office Action states that "embolus" should be deleted after "member" at claim 110, line 13; that in claim 111, step E cannot be performed before step C; and that method claim 128 depends from apparatus claim 119.

As indicated herein, claim 110 has been amended by deleting "embolus", as the Examiner suggested; claim 111 has been canceled; and claim 128 has been amended to be dependent from claim 127. Accordingly, Applicant submits that the rejections have been overcome.

Claims 104, 111-114, 121, and 127-130 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that was not described in the specification. As set forth above, claims 104, 111, and 121 have been canceled. Therefore, the rejections of these claims is rendered moot.

Regarding the rejection of claim 112, Applicant respectfully traverses the rejection. Claim 112 indicates that step E as recited in claim 110 is performed after step C of claim 110. This is supported by the specification at least at Figures 9-12, and the related description. Figure 9 illustrates an assembly beginning d ployment of an IFM in a vessel. Figure 10 illustrates th ass mbly completing deployment of the IFM in a vessel. Figure 12 illustrates a thrombogenic device placed in a vessel defect after the IFM has been

deployed in the vessel. Accordingly, Applicant submits that claim 112 is clearly described within the specification to satisfy the requirements of 35 U.S.C. 112, first paragraph.

Regarding the rejection of claims 113 and 114, Applicant has amended the specification as set forth above in response to Item 1, above. Applicant submits that th amendments to the specification do not introduce new matter, and provide a written description of claims 113 and 114 to satisfy 35 U.S.C. § 112.

Regarding the rejections of claims 127-130, Applicant has amended claim 127 to recite that the apparatus is positioned in the blood vessel to direct blood flow from the defect, and has amended claim 128 to recite that the apparatus modifies blood flow to strengthen the blood vessel with the aneurysm. These amendments similarly apply to claims 129 and 130, which are dependent from claim 128. The amendments to the claims are supported by the specification, including the figures. Applicant respectfully submits the rejections under 35 U.S.C. § 112, first paragraph have been overcome.

Items 3 of the Office Action - Claim Rejections Under 35 U.S.C. §§ 102 and 103

Claims 102-105, 108-111, 115, 116, and 118 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by, or in the alternative, as allegedly obvious over Forber et al. (U.S. Patent No. 5,733,294).

Applicant does not hereby indicate any agreement with the grounds for this rejection stated in the Office Action. However, to advance the prosecution of the subject application, Applicant has amended claims 102 and 110 to indicate that the intravascular member defin s a blood flow channel that permits blood to flow through the intravascular member when it is positioned in the blood vess l. Applicant respectfully traverses the rejection as it pertains to the amended claims set forth herein.

Additionally, by this amendment, Applicant has amended independent claim 102 to state that when the intravascular member is in its collapsed configuration it comprises and elongate strand member. Similar limitations requiring the intravascular apparatus to be substantially linear when in its collapsed configuration have been added to the other independent claims. None of the prior art of record, including the publication cited in the accompanying supplemental IDS, are believed to teach or suggest a method or apparatus for treating a vessel wall defect such as an aneurysm which includes all of the limitations recited in the independent claims, as now amended.

Specifically, Forber does not disclose or even suggest an apparatus, or a method of using an apparatus, that includes an intravascular member that defines a blood flow channel, let alone an apparatus that includes such an intravascular member in combination with an embolus member, as recited in the claims. In contrast, Forber actually teaches away from such an apparatus. Forber actually discloses a device that occludes (i.e., prevents blood flow) blood vessels (see, for example, column 1, lines 54-67; column 2, lines 19-20; column 2, lines 23-24; column 3, lines 35-39; and column 6, lines 23-24). Because Forber fails to disclose or suggest an apparatus or method, as recited in the pending claims, and because Forber actually teaches away from the claimed invention, Applicant submits that Forber does not anticipate or make obvious the pending claims.

Sawyer teaches a stent having a single, helical coil wherein each of the loops of th coil are laterally adjacent to the other loops along the length of the stent so that the stent has a uniform thickness and cross sectional area (see Figure 1 and column 4, lines 11-13). Sawyer actually teaches away from positioning a coil within another coil since that positioning may alter the flow of blood through the stent attempted to be achieved by Sawyer. Sawyer specifically states that the utility of his stent is for "increasing blood flow velocity without creating turbulence of stagnant areas". (Column 4, lines 24-25). Providing

a coil within at least one other coil of Sawyer's stent may affect the airfoil created by Sawyer's specific design, and thus, Sawyer does not render the claimed invention obvious.

Applicant respectfully submits that the pending claims are in condition for allowance, and issuance of a Notice of Allowance is earnestly solicited. The Examiner is encouraged to contact the undersigned by telephone if there is believed to be any further impediment to allowance of the present application.

Respectfully submitted,
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Date: September 24, 2002

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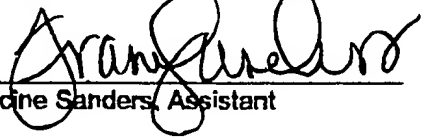
I hereby certify that this correspondence is being filed in the United States Patent Office by facsimile [(703) 305-3590 on September 24, 2002.

Dated: September 24, 2002

By: 
Francine Sanders, Assistant

APPENDIX SETTING FORTH AMENDMENTS IN MARKED-UP FORMAT

In the Specification:

The following paragraph has been inserted before the paragraph beginning at page 34, line 16:

In another method, as illustrated in Figure 12, an embolus member may be positioned within the vessel wall defect and retained by the intravascular member. As shown in Figure 12, the embolus member may be delivered from a catheter that is disposed within the intravascular member after it has been radially expanded. In particular, the delivery catheter, such as microcatheter 70, as shown in Figure 10, may be positioned so that its distal end is within intravascular member 20, and may then be advanced so that the distal end of microcatheter 70 extends through a portion of intravascular member 20 into vessel wall defect 34. For example, the distal end of the delivery catheter may be advanced through a space between two adjacent convolutions of the helical coil of intravascular member 20 (as shown in Figure 12). The embolus member may then be directed out of the distal end of microcatheter 70. After the procedure, the delivery catheter, such as microcatheter 70, may be removed from intravascular member 20 so that the embolus member is left within vessel wall defect 34 and which is prevented from escaping from the vessel wall defect into the lumen of the blood vessel by the positioning of the intravascular member in the blood vessel.

In the Claims:

Claims 104, 111, 121, 126, and 131 have been canceled.

Claims 102, 103, 105-110, 112-120, 122-125, and 127-130 have been amended as follows:

102 [103]. (Amended) Apparatus for implantation in a blood vessel that has a vessel wall, a vessel lumen defined by the vessel wall [, a wall and a vessel wall defect] and an aneurysm formed in the vessel wall in communication with the vessel lumen, said apparatus comprising:

an intravascular member that has a [radially] collapsed configuration wherein it is in the form of an elongate strand member of a first diameter and [a radially] an expanded configuration wherein the elongate strand member assumes a curved configuration which generally defines a tubular shape of a second diameter, said intravascular member being advanceable while in its [radially] collapsed configuration to a position within the vessel lumen [of the blood vessel] adjacent to the aneurysm [vessel wall defect] and then expandable to its [radially] expanded configuration [confuguration] wherein it engages the vessel wall and is thereby held in substantially fixed position within the vessel lumen [of the blood vessel] adjacent to the aneurysm [vessel wall defect], and wherein the intravascular member defines a blood flow channel that permits blood to flow through the intravascular member while it is positioned in the blood vessel; and,

an embolus member that is transluminally advanceable through the lumen of th blood vessel and placeable within the aneurysm [vessel wall defect];

the intravascular member being operative to prevent the embolus member from escaping from the aneurysm [vessel wall defect] and into the vessel lumen [of the blood vessel].

103 [104]. (Amended) Apparatus according to Claim 102 [103] wherein the intravascular member self expands from its [radially] collapsed configuration to its [radially] expanded configuration.

105 [106]. (Amended) Apparatus according to Claim 102 [103] wherein the intravascular member comprises a helical coil when in its expanded configuration.

106 [107]. (Amended) Apparatus according to Claim 102 [103] wherein the intravascular member comprises an outer layer and an inner layer when in its expanded configuration.

107 [108]. (Amended) Apparatus according to Claim 106 [107] wherein the outer layer and the inner layer are formed of a continuous strand.

108 [109]. (Amended) Apparatus according to Claim 102 [103] wherein the intravascular member is formed of a shape memory alloy.

109 [110]. (Amended) Apparatus according to Claim 102 [103] wherein the embolus member comprises a thrombogenic member.

110 [111]. (Amended) A method for treating a defect in the wall of a blood vessel that has a lumen and a wall, said method comprising the steps of:

A. providing an intravascular member that has a radially collapsed configuration wherein it is in the form of a substantially linear member of a first diameter and a radially expanded configuration wherein it is in the form of a generally tubular member of second diameter;

B. transluminally advancing the intravascular member, while in its radially collapsed configuration, into the blood vessel and to a position within the

blood vessel lumen adjacent to the vessel wall defect;

C. radially expanding the intravascular member to its radially expanded configuration such that it engages the wall of the blood vessel and is thereby held in substantially fixed position within the vessel lumen adjacent to the vessel wall defect and so that it provides a blood flow channel to permit blood to flow past the intravascular member when it is positioned in the blood vessel;

D. providing an embolus member sized to fit within the vessel wall defect;

E. positioning the embolus member within the vessel wall defect such that the intravascular member [embolus] retains the embolus member [withing] within the vessel wall defect.

112 [113]. (Amended) A method according to Claim 110 [111] wherein Step E is performed after Step C.

113 [114]. (Amended) A method according to Claim 112 [113] wherein Step E comprises:

i positioning a delivery catheter having a distal end within the intravascular member after it has been radially expanded in Step C;

ii causing the distal end of the delivery catheter to advance through a portion of the intravascular member and into the vessel wall defect;

iii delivering the embolus member out of the distal end of the delivery catheter and into the vessel wall defect; and,

iv removing the delivery catheter, leaving the embolus member within the vessel wall defect with the intravascular member preventing the embolus member from escaping from the vessel wall defect into the lumen of the blood vessel.

114 [115]. (Amended) A method according to Claim 113 [114] wherein the intravascular member comprises a helical coil having a plurality of convolutions with spaces therebetween and wherein step ii comprises advancing the distal end of the delivery catheter through a space between two adjacent convolutions of the helical coil and into the vessel wall defect.

115 [116]. (Amended) A method according to Claim 110 [111] wherein the vessel wall defect is an aneurysm and wherein Step E comprises positioning the embolus member within the aneurysm.

116 [117]. (Amended) A method according to Claim 115 [116] wherein the aneurysm is a wide mouthed aneurysm and wherein Step E comprises delivering the embolus member through the mouth of the aneurysm and into the aneurysm sac.

117 [118]. (Amended) A method according to Claim 115 [116] wherein the aneurysm is a cerebral aneurysm.

118 [119]. (Amended) A method according to Claim 110 [111] wherein the embolic member delivered in Step E comprises a thrombogenic member.

119 [120]. (Amended) An intravascular flow modifier apparatus for treating a defect in a blood vessel wall into which blood flows from the lumen of the blood vessel, said apparatus comprising:

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at least one biocompatible member that is initially disposable in a collapsed substantially linear configuration and is thereafter transitionable to an expanded configuration, when in its expanded configuration said at l ast one memb r defining a blood flow channel and a flow modification region, the blood flow channel being defined by a plurality of coils with at least one of the coils disposed within at least one of the other

coils;

said intravascular flow modifier apparatus being deliverable, while in its collapsed substantially linear configuration, through the blood vessel lumen to a location within th blood vessel lumen adjacent to the vessel wall defect and said apparatus being thereafter transitionable to its expanded configuration such that blood flowing through the lumen of the blood vessel may flow through the blood flow channel of the apparatus and the flow modifying region of the apparatus is positioned adjacent to the vessel wall defect so as to modify blood flow from the lumen of the blood vessel into the vessel wall defect.

120 [121]. (Amended) An apparatus according to Claim 119 [120] wherein the biocompatible member self- expands from its [radially] collapsed substantially linear configuration to its [radially] expanded configuration.

122 [123]. (Amended) An apparatus according to Claim 119 [120] wherein the biocompatible member comprises a helical coil.

123 [124]. (Amended) An apparatus according to Claim 119 [120] wherein th biocompatible member comprises an outer layer and an inner layer.

124 [125]. (Amended) An apparatus according to Claim 123 [124] wherein the outer layer and the inner layer are formed of a continuous strand.

125 [126]. (Amended) An apparatus according to Claim 119 [120] wherein the biocompatible member is formed of a shape memory alloy.

127 [128]. (Amended) A method for treating a defect in a wall of a blood vessel that has a lumen and a wall, th method comprising the steps of:

A. providing an apparatus that i) is initially disposable in collapsed

substantially linear configuration and is thereafter transitionable to an expanded configuration and ii) when in its expanded configuration comprises a blood flow channel and a flow modification region, the blood flow channel being defined by a plurality of coils with at least one of the coils disposed within at least one of the other coils;

B. positioning the apparatus, while in its collapsed configuration, within th lumen of the blood vessel adjacent to the defect;

C. positioning and expanding the apparatus to its expanded configuration such that i) the apparatus engages the wall of the blood vessel to hold the apparatus in a substantially stationary position within the blood vessel lumen, ii) blood flowing through the blood vessel lumen passes through the blood flow channel of the apparatus and iii) the flow modifying region of the apparatus is positioned relative to the defect to divert blood flow from the defect [decrease blood pressure within the defect].

128 [129]. (Amended) A method according to Claim 127 [120] wherein the vessel wall defect is an aneurysm, Step B comprises positioning the apparatus within the blood vessel lumen adjacent to the aneurysm and Step C comprises positioning and expanding the apparatus such that the apparatus modifies blood flow in a way that strengthens the blood vessel with the aneurysm [decreases strain on the aneurysm].

129 [130]. (Amended) A method according to Claim 128 [129] wherein the aneurysm is a wide mouthed aneurysm and Step C comprises positioning and expanding the apparatus such that the flow modifying region is next to the mouth of the aneurysm.

130 [131]. (Amend d) A m thod according to Claim 128 [129] wherein the aneurysm is a cerebral aneurysm.